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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 070231 0019 Rev. 03

Certificate Holder: **Spacelabs Healthcare Ltd.**
Unit B, Foxholes Centre
John Tate Road
Hertford, Hertfordshire SG13 7DT
UNITED KINGDOM

Certification Mark:

Scope of Certificate: **Design, Manufacture and Service of ECG Recorders, Ambulatory ECG and NIBP Recorders and Receiving Stations, ECG Analysers, ECG Stress Test Systems, Cardiac Information Management Systems, Anaesthetic and Ventilation Equipment**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 070231 0019 Rev. 03
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002959**
Report No.: **75958983**
Effective Date: **2024-02-09**
Expiry Date: **2027-02-08**

Date of Issue: 2023-12-15

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada
- Medical Device Regulations – Part 1- SOR 98/282

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

Spacelabs Healthcare Ltd.
Unit B, Foxholes Centre, John Tate Road, Hertford, Hertfordshire SG13 7DT, UNITED KINGDOM

Spacelabs Healthcare Ltd.
43 Moray Place, Edinburgh, Lothian EH3 6BT, UNITED KINGDOM

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C E R T I F I C A T E

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